

R E M A R K S

Claim Amendments and New Claim

Claims 10, 11 and 13 were canceled hereinabove.

The features of claim 10 were included in claim 12  
(currently amended).

New claim 14 was added. Claim 14 includes subject matter of  
amended claim 12 and previous claim 13.

Editorial revisions were made to conform claim 12 to the  
Examiner's characterization of the presently claimed invention on  
page 4, lines 13 to 18 of the Office Action.

Rule 116

With respect to 37 CFR 1.116, it is noted that the above  
claim amendments and new claim include features that were  
included in the claims prior to the final rejection. Also, it is  
noted that the total number of claims has not been increased. It  
is therefore respectfully requested that the claim amendments and  
new claim be entered.

Rejection Under 35 USC 112, First Paragraph

Claims 10 and 11 were rejected under 35 USC 112, first paragraph, for the reasons set forth on pages 2 to 3 of the Office Action, referring to the written description requirement.

The subject matter of claim 10 was combined with claim 12, as noted above. Claims 10 and 11 were canceled above. This renders the 35 USC 112, first paragraph rejection moot.

It is respectfully submitted that claim 12 and new claim 14 are free of the 35 USC 112, first paragraph rejection.

Withdrawal of the 35 USC 112, first paragraph rejection is respectfully requested.

Applicants' Presently Claimed Invention

Applicants' present claims are directed to a prostaglandin-containing product comprising an aqueous liquid preparation containing a prostaglandin F2 $\alpha$  derivative having a fluorine atom or fluorine atoms in a molecule and a resin container containing the aqueous liquid preparation, the resin container being formed from a polymer alloy of polyethylene terephthalate and polyarylate, wherein a component ratio of polyethylene terephthalate/polyarylate is 1/2 to 2/1, thereby inhibiting the

decrease of the content of the prostaglandin F2 $\alpha$  derivative in the aqueous liquid preparation.

The presently claimed invention, as described in "Disclosure of the Invention" and the "examples" in the present specification, takes into account the material that a container for an eye drop is made of, and is based on the finding that a decrease of the content of a prostaglandin F2 $\alpha$  isopropyl ester contained in the container can be significantly inhibited. This significant inhibition is brought about by storing a prostaglandin F2 $\alpha$  derivative, such as 16-phenoxy-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2 $\alpha$  isopropyl ester, in a resin container formed from a polymer alloy of polyethylene terephthalate and polyarylate, wherein a component ratio of polyethylene terephthalate/polyarylate is 1/2 to 2/1 (for example, wherein said component ratio is 45/55 as disclosed at the middle of page 12 of the present specification).

#### Obviousness Rejection Under 35 USC 103

Claims 10 to 13 were rejected under 35 USC 103 as being unpatentable over Morishima et al. (WO 02/22131) (using US 2004/0097592 as a translation) in view of Koide et al. (JP 7-33650) for the reasons set forth on pages 4 to 6 of the Office Action.

The Morishima et al. reference was cited to teach prostaglandin F2 $\alpha$  derivatives. However, it was admitted in the Office Action that Morishima et al. do not specifically teach a resin container containing a copolymer of polyethylene terephthalate and polyarylate with a ratio of 1:2 to 2:1.

The Koide et al. reference was cited with respect to a resin container and a generic disclosure of inhibiting photolysis and adhesion of vitamin A to the container.

It was also admitted in the Office Action that the references do not specifically teach adding the ingredients in the ratio as claimed by the applicants. However, the position was taken in the paragraph bridging pages 5 to 6 of the Office Action that the amounts of ingredients in a polymer is a routine optimization of parameters to obtain a resultant effective parameter. It is respectfully submitted that the Office Action failed to teach or suggest a reason in the art to optimize to the claimed parameter for the claimed compounds with an expectation of success required by the present claims.

As discussed above, applicants' present claims recite a resin container containing a polymer mixture of polyethylene terephthalate and polyarylate, wherein a component ratio of

polyethylene terephthalate/polyarylate is 1/2 to 2/1. For a specific object, without a reason to optimize the parameter with an expectation of success, the Examiner's statement does not support a case of obviousness.

In contrast to the presently claimed invention, the Morishima et al. reference (WO 02/22131) discloses an invention which focuses on additives of an eye drop, and discloses that the absorption of prostaglandin derivatives on a resin container can be inhibited by adding an additive (polysorbate 80 or ethylenediamine-tetraacetate) to an eye drop comprising prostaglandin derivatives.

The Morishima et al. reference (WO 02/22131) is thus characterized in adding an additive such as polysorbate 80 or ethylenediamine-tetraacetate to an eye drop to inhibit absorption on a resin container, whereas the presently claimed invention is characterized in using a polymer alloy of polyethylene terephthalate and polyarylate in a particular ratio range as a material for a container for an eye drop to inhibit a decrease of the content of specific prostaglandin F2 $\alpha$  derivatives. Accordingly, Morishima et al. and the presently claimed invention are totally different.

Furthermore, since the Morishima et al. reference (WO 02/22131) does not teach or suggest that a container made of a polymer mixture of polyethylene terephthalate and polyarylate inhibits the decrease of the content of 16-phenoxy-15-deoxy-15, 15-difluoro-17,18,19,20-tetranorprostaglandin F2 $\alpha$ , 16-(3-chlorophenoxy)-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2 $\alpha$ , or 16-phenoxy-15-deoxy-15, 15-difluoro-13,14-dihydro-17,18,19,20-tetranorprostaglandin F2 $\alpha$ , Morishima et al. (WO 02/22131) alone or combined with Koide et al. (discussed hereinbelow) would not lead to the presently claimed invention.

The Koide et al. reference (JP 7-33650) is characterized in that vitamin A is contained in a container made of polyethylene terephthalate, containing a pigment or pigments and a U-polymer (polyarylate), to inhibit the migration of vitamin A, which is unstable in light.

Thus, since the container of Koide et al. (JP 7-33650) includes vitamin A, whereas the container of the presently claimed invention includes 16-phenoxy-15-deoxy-15,15-difluoro-17, 18,19,20-tetranorprostaglandin F2 $\alpha$ , 16-(3-chlorophenoxy)-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2 $\alpha$ , or

16-phenoxy-15-deoxy-15,15-difluoro-13,14-dihydro-17,18,19,20-tetranorprostaglandin F2 $\alpha$ , it is clear that the chemicals in the respective containers include compounds that have completely different chemical structures and chemical properties.

Furthermore, Koide et al. describe in paragraph [0008] that the fourth essential constituent of Koide et al. is a pigment which may have a high light shielding effect, such as tinuvin or anthraquinone yellow dye. Koide et al. also disclose that when the light shielding wavelength is less than 380nm, even after the addition of the pigment, the vitamin A therein decreases significantly after a long period.

Moreover, as is clear from Table 2 of Koide et al. (JP 7-33650), although Comparative Example 4 includes polyethylene terephthalate and a U-polymer as materials of a container, the concentration (residual ratio) of vitamin A is merely 26%. Considering that Koide et al. describe the comparison as an example, wherein no stabilizing effect of vitamin A is exhibited, it is respectfully submitted that from the disclosure of Koide et al., one of ordinary skill in the art would not consider to replace the vitamin A of Koide et al. with 16-phenoxy-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2 $\alpha$ , 16-(3-

chlorophenoxy)-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2 $\alpha$ , or 16-phenoxy-15-deoxy-15,15-difluoro-13,14-dihydro-17,18,19,20-tetranorprostaglandin F2 $\alpha$  recited in applicants' present claims.

As stated above, since the disclosures of Morishima et al. (WO 02/22131) and Koide et al. (JP 7-33650) are both completely different in structure from the presently claimed invention, and since Morishima et al. and Koide et al. do not describe or suggest that a decrease of the content of the prostaglandin F2 $\alpha$  can be inhibited by storing 16-phenoxy-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2 $\alpha$ , 16-(3-chlorophenoxy)-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2 $\alpha$ , or 16-phenoxy-15-deoxy-15,15-difluoro-13,14-dihydro-17,18,19,20-tetranorprostaglandin F2 $\alpha$  in a resin container formed from a polymer alloy of polyethylene terephthalate and polyarylate, having a component ratio of polyethylene terephthalate/polyarylate of 1/2 to 2/1, applicants' present claims would not be arrived at if Morishima et al. (WO 02/22131) and Koide et al. (JP 7-33650) are combined.

Withdrawal of the 35 USC 103 rejection is therefore respectfully requested.



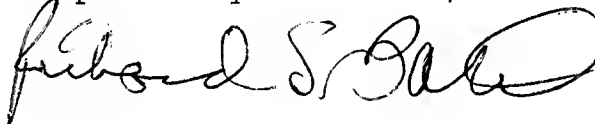
Reconsideration is requested. Allowance is solicited.

It is noted that WO 02/22106 to Wong and EP 1 321 144 to Morishima et al. were applied in a prior art rejection in the June 17, 2010 Office Action in copending related application Serial No. 11/821,511.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

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Respectfully submitted,



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